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 PATENT, TRADEMARK, COPYRIGHT  
 AND UNFAIR COMPETITION LAW  
 AND RELATED LITIGATION

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 TRUMAN A. HERRON 1935-1976  
 EDWARD B. EVANS 1936-1971

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## FACSIMILE COVER SHEET

To: Commissioner for Patents  
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From: David E. Jefferies  
 Re: Serial No: 09/765,151  
 Filing Date: January 17, 2001  
 Applicant: Gilbert R. Gonzales, et al.  
 Title: COMBINATION AND  
 METHOD INCLUDING A VISUAL  
 MARKER FOR DETERMINING  
 COMPLIANCE WITH A  
 MEDICATION REGIMEN  
 Our File: PEDI-27

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## MESSAGE/COMMENTS

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Application Serial No. 09/765,151  
Amendment dated March 18, 2005  
Reply to Office Action dated November 18, 2004

amendment may be found at least in originally filed claim 20. Applicants submit that the half-life of the colorant in Singh (based on the amounts disclosed) would not be similar to, and thus comparable to, the half-life of the composition. This, again, is because the colorant of Singh is only present in a small amount to be used as an optional component. Likewise, the half-life of the colorant in Blase would not be similar to, and thus comparable to, the half-life of the composition.

Also, the Examiner cites Blase for its disclosure of multiple dyes (being multiple markers). Applicants disagree. The purpose of using multiple dyes in one composition in Blase is to mix two colors to produce a third color for the suspension (see column 10, lines 6-9, discussing the mixing of blue and red coloring agents to provide a purple color to the composition). This in no way discloses multiple markers as described in the present application (for example, see p. 17, lines 6-16 of the application, disclosing a composition including a first marker detectable under natural light and a second marker detectable only under light that causes fluorescence, wherein each marker has a different duration).

Thus, neither Singh nor Blase discloses a marker provided in a sufficient amount and form to cause a contact coloration of at least a portion of the oral and/or pharyngeal cavity for determining whether a patient is in compliance with a medication regimen. Thus, any combination of Singh and Blase does not disclose this limitation of claim 15, which is incorporated in claims 23 and 25-27. Thus, claims 23 and 25-27

Other visual inspection methods might be used. For example, fluorescence of the oral cavity or portion thereof could be detected using a fluorescent light. The light would evoke a visually apparent emission of fluorescence of a characteristic color for the particular marker used. The fluorescence would remain detectable for a period of hours, such that inspection may be made after the marker color is no longer significantly visible to the naked eye.

The use of an orally ingested and visible marker provides a qualitative determination of a patient's compliance with a medication regimen. In providing for this determination rapidly, visually, and without intrusion of the patient's privacy, the present invention eliminates the drawbacks of the prior art. The marker can be directly visually detected soon after oral administration of the medication or may be detected some time later by fluorescing the residue of the marker in the oral cavity.

The marker indicates to a primary caregiver, guardian, or family member whether the medication was orally ingested during a recent period of time. The presence of discoloration of the oral cavity caused by the marker is the specific information to notify the caregiver that the medication was actually orally ingested. The physical act of checking on the compliance of the medication delivery associated with the invention will also improve medication delivery.

For example, the invention will alter noncompliant behavior by notifying the patient that compliance is being monitored. Should noncompliance persist, that information would allow a caregiver to alter the methods of medication delivery. For example, a child in school or daycare who requires daytime dosing of an antibiotic for recurrent ear infections could be given an antibiotic containing the marker. The child could then be checked for ingestion compliance immediately after